UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

THOMAS JOSHUA HOFFERTH, an individual, PLAINTIFF, V. JANSSEN PHARMACEUTICALS, INC.; JANSSEN, L.P.; JOHNSON & JOHNSON; JANSSEN RESEARCH AND DEVELOPMENT, LLC; DEFENDANTS.	CIVIL ACTION NO.: 3:17-1560-TLW **COMPLAINT FOR DAMAGES** JURY TRIAL DEMANDED

COMES NOW Plaintiff alleges against Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research and Development, LLC as follows:

INTRODUCTION

1. This is an action for damages relating to the Defendants' design, manufacture, sale, marketing, advertising, promotion, and distribution of Risperdal (risperidone) and Invega (paliperidone – the primary active metabolite of risperidone). Risperdal in any of its forms (including generic risperidone) shall herein be referred to as "Risperdal."

2. The use of Risperdal and Invega can cause rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), tardive dyskinesia, and other serious health conditions.

3. Plaintiff ingested or was injected with Risperdal and/or Invega, and as a result of his use of Risperdal and/or Invega suffered injuries.

GENERAL ALLEGATIONS

4. Plaintiff, Thomas Joshua Hofferth ("Plaintiff"), by and through Plaintiff's attorneys, Hatfield Temple, LLP, and Sanders Phillips Grossman, LLC brings this action for personal injuries suffered by Plaintiff, as detailed more fully herein, suffered as a proximate result of Plaintiff being prescribed and ingesting the defective and unreasonably dangerous prescription drug(s) Risperdal and/or Invega.

5. Risperdal and Invega are antipsychotic medications and were originally developed and approved for use in the treatment of symptoms associated with adult schizophrenia. At all times relevant hereto, Risperdal and Invega were manufactured, designed, tested, packaged, labeled, marketed, advertised, promoted, distributed, and sold by Defendants Janssen Pharmaceuticals; Inc. Janssen, L.P. and Johnson & Johnson; and Janssen Research and Development, LLC. On information and belief, Plaintiff ingested Risperdal and Invega resulting in injuries.

6. Plaintiff makes the following allegations based upon personal knowledge and upon information and belief, as well as upon investigative efforts regarding events surrounding the ingestion of the prescription drug, Risperdal and Invega, by Plaintiff.

PARTIES

7. At all times relevant to this action, Plaintiff, was an individual, citizen and resident of South Carolina.

8. Plaintiff ingested Risperdal from approximately July 2001 to January 2002, resulting in injuries.

9. Plaintiff ingested Invega from approximately September 2008 to July 2010, resulting in injuries.

10. Defendant Janssen Pharmaceuticals, Inc. is the successor in interest to Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Ortho-McNeil Pharmaceutical Products, Inc.; Janssen, LP former known as Janssen Pharmaceutica Products, L.P.; and Janssen Pharmaceutical Products, L.P., (with Janssen Pharmaceuticals, Inc., hereinafter collectively referred to as "Janssen") and is a Pennsylvania corporation and subsidiary of Johnson & Johnson Company. At

all relevant times, Janssen regularly and continuously did business within this judicial district including labeling, packaging, marketing, advertising, distributing and selling Risperdal and Invega.

11. Johnson & Johnson is a corporation organized and existing under the laws of New Jersey with its principal place of business in New Jersey. At all relevant times, Defendant Johnson & Johnson regularly and continuously did business within this judicial district including labeling, packaging, marketing, advertising, distributing and selling Risperdal and Invega.

12. Several affiliates have provided Janssen with support in the development and distribution of Risperdal and/or Invega. These affiliates include Janssen Research and Development, LLC formerly known as Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Pharmaceutical Sourcing-Group Americas, Pharmaceutical Group Strategic Marketing, Janssen Pharmaceutica N.V., Janssen Ortho LLC, Janssen Medical Affairs, L.L.C., and Ortho-McNeil Janssen Scientific Affairs, L.L.C. All of these entities are subsidiaries or divisions of Defendants Janssen and/or Johnson & Johnson, and regularly and continuously do business throughout California, including in this judicial district.

13. Defendant Janssen Research and Development, LLC (hereinafter "JRD") is a New Jersey limited liability company. JRD was responsible for clinical research and development of Risperdal and Invega, for pharmacovigilance in the United States pertaining to Risperdal, and for submitting regulatory reports to the United States Food & Drug Administration (hereinafter "FDA") pertaining to Risperdal and Invega. JRD regularly and continuously does business within California and throughout the United States.

14. Hereinafter the aforementioned Defendants may collectively be referred to as "Defendants."

15. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

16. At all relevant times, Defendants acted in concert with one another in the District of South Carolina to fraudulently convey false and misleading information concerning the safety and efficacy of Risperdal and Invega and to conceal the risks of serious adverse events, including

weight gain, hyperprolactinemia, gynecomastia, tardive dyskinesia, and other adverse effects associated with Risperdal and Invega from the public, Plaintiff, physicians, and other healthcare providers. These concerted efforts resulted in significant harm to those treated with Risperdal or Invega, including Plaintiff. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiff would not have ingested or permitted injections of Risperdal or Invega.

17. At all times alleged herein, Defendants were engaged in the business of, or were successors-in-interest to entities engaged in the business of, researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising for sale or selling Risperdal.

18. At all times alleged herein, Defendants were authorized to conduct or engage in business within the District of South Carolina and supplied Risperdal within the state of South Carolina. Defendants received financial benefit and profits as a result of designing, manufacturing, marketing, advertising, selling and distributing Risperdal within the state of South Carolina.

19. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

20. The amount in controversy exceeds the jurisdictional limits of this court.

JURISDICTION AND VENUE

21. Jurisdiction is proper in this court pursuant to 28 USC § 1332 as complete diversity of citizenship exists between Plaintiff and Defendants and the matter in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

22. This Court has jurisdiction over the non-resident Defendants because they have conducted business in the District of South Carolina. Defendants have committed a tort in whole or in part in the District of South Carolina and have regular and continuing contacts with South Carolina.

23. At all times material hereto, Defendants maintained systematic and continuous contacts in this judicial district, regularly transacted business within this judicial district, employed numerous individuals in this district and regularly availed themselves of the benefits of this judicial district. Defendants received substantial financial benefit and profits as a result of designing, manufacturing, marketing, advertising, selling and distributing Risperdal and Invega in this district and throughout the United States.

24. In addition, venue of this case is proper in the District of South Carolina pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred in state of South Carolina.

FACTUAL ALLEGATIONS

A. RISPERDAL AND INVEGA PRODUCTS

25. Risperdal and Invega are antipsychotic medications belonging to a class of drugs which have become known as "atypical" or "second generation" ("SGA") antipsychotics. Other atypical antipsychotics include Clozaril (clozapine), Seroquel (quetiapine), Zyprexa (olanzapine), Geodon (ziprasidone), Abilify (aripiprazole), all of which began entering the market in 1989 and thereafter.

26. Risperdal was originally developed and approved for use in the treatment of symptoms associated with adult schizophrenia. However, Risperdal and Invega do not cure schizophrenia or any other mental health condition. The pharmacologic action of Risperdal and Invega is dependent on their ability to block or moderate the level of dopamine, a chemical

found in the brain, which in excessive amounts is believed to cause abnormal thinking and hallucinations.

27. A serious side effect of Risperdal and Invega is that the medications increase the level of prolactin in the blood. This side effect is called hyperprolactinemia. Prolactin is a protein hormone that stimulates breast growth and milk secretion, normal processes during pregnancy and lactation. In males, however, hyperprolactinemia can lead to the development of female breasts, an irreversible condition known as gynecomastia.

28. Risperdal and Invega can and do cause other serious and sometimes fatal injuries to the metabolic, cerebrovascular, neurologic, and endocrine systems and to organs such as the brain, liver and pancreas in some patients. In addition to hyperprolactinemia and gynecomastia, other adverse effects include, but are not limited to, rapid weight gain, galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akathisia, parkinsonism, rhabdomyolysis, and other related conditions. Complications of diabetes mellitus include ketoacidosis, hyperosmolar coma, heart disease, infection, neuropathy, blindness, seizures, and death.

B. FDA APPROVED INDICATIONS

29. On December 29, 1993, Janssen obtained approval from the FDA to market Risperdal oral tablets for the treatment of "manifestations of psychotic disorders" in adults with a target dosage of 4 to 6 milligrams per day. The approved label explained that "[t]he antipsychotic efficacy of Risperdal® was established in short-term (6 to 8 weeks) controlled trials in schizophrenic inpatients."

30. In September 2000, the FDA requested that the label be changed to more clearly indicate that Risperdal was only approved for use in treating schizophrenia in adults.

31. On March 3, 2002, the FDA approved revised labeling for Risperdal to state that Risperdal is indicated for "the treatment of schizophrenia." The indication continued to be only for adult patients.

32. The FDA subsequently approved other Risperdal formulations for the treatment of schizophrenia in adults ─ on April 2, 2003, the FDA approved the Risperdal M-Tab for adults; and on October 29, 2003 the FDA approved Risperdal CONSTA, a long-acting injection form of Risperdal for adults.

33. On December 4, 2003, the FDA approved Risperdal for the short-term treatment of acute manic or mixed episodes associated with Bipolar I disorder in adults.

34. Between 1993 and late 2006, Risperdal was not approved by the FDA for any other indications in adults other than schizophrenia and Bipolar I disorder. More importantly, for that same time period, Risperdal was not approved for use in children for any purpose.

35. In October 2006, Risperdal was for the first time approved for a very limited indication for use in children and adolescents. The approved indication was for the treatment of a specific condition called irritability associated with autistic disorder in children and adolescents between the ages of 5 and 16. The FDA only granted approval for this specific condition associated with autism; it did not give approval for the whole Autistic Spectrum Disorder.

36. On August 22, 2007, Risperdal was approved for the additional limited indications of schizophrenia in adolescents ages 13 to 17 years, and for the short-term treatment of acute manic or mixed episode associated with Bipolar I disorder in children and adolescents ages 10 to 17 years.

37. At no time has Risperdal or Invega been approved for any other child or adolescent indication than those stated above. Risperdal and Invega have never been approved for the whole Autistic Spectrum Disorder, Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, or any other child or adolescent indication.

C. FDA PROHIBITION OF OFF-LABEL MARKETING AND PROMOTION

38. Under the FDA laws and regulations, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose (a purpose that is

not approved by the FDA), and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which, by definition, includes all promotional, marketing and advertising material from the drug manufacturer) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

39. If a drug manufacturer markets or promotes its drug for an unapproved use, it is guilty of "misbranding" or off-label promotion.

40. In order to control indirect promotion of off-labels uses by manufactures, Congress and the FDA promulgated laws and regulations designed to regulate two of the most prevalent indirect promotional strategies used by drug companies to market their drugs for unapproved off-label uses: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education ("CME") programs that advocate off-label uses of their drugs.

41. With regard to the first practice of a drug company disseminating written information about its drug, the FDA permits a manufacturer to disseminate information regarding off-label usage only in response to an unsolicited request from a health care practitioner. In any other circumstance, a manufacturer cannot disseminate information concerning the off-label uses of a drug to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or federal and state government agencies unless such information is fair and balanced and the manufacturer meets all the following conditions:

a. The information concerns a drug that has been approved, licensed and cleared for marketing by the FDA.

b. The information is in the form of an unabridged copy of a peer-reviewed scientific or medical journal article or reprint, or an unabridged reference publication that pertains to a clinical investigation involving the drug and that is

considered scientifically sound by experts who are qualified to evaluate the product's safety or effectiveness;

c. The information does not pose a significant risk to the public health;

d. The information is not false or misleading; and

e. The information is not derived from clinical research conducted by another manufacturer, unless permission is received from that manufacturer.

42. With regard to the second practice – manufacturer involvement in CME programs – the FDA's examination of these practices led to the publication of an agency enforcement policy in 1997, entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities." 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.)(1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. The promotion of off-label drug uses at a CME program which fails the test of "independence" violates Congress' off-label marketing restrictions.

43. From 1993 through 2006, off-label uses of Risperdal continued to increase, especially in the child and adolescent sector. According to a 2006 analysis published in the Archives of Internal Medicine (see Boost for Off-Label Drug Use, Wall Street Journal, February 16, 2008), Risperdal was used off-label 66% of the time in 2006. Today, according to published market research data, as many as 70% of the prescriptions for Risperdal are for off-label use.

D. THE RISPERDAL LABEL AND COMMUNICATIONS WITH THE FDA

44. On August 15, 1996, Janssen asked the FDA to approve an addition of language to the Risperdal label regarding pediatric use. The FDA rejected Janssen's request, stating: "[Y]ou have not identified any pediatric indications for which you believe Risperdal could be approved and you have provided no data from adequate and well controlled trials to support any

such approvals ... To permit the inclusion of the proposed vague references to the safety and effectiveness of Risperdal in pediatric patients and the nonspecific cautionary advice about how to prescribe Risperdal for the unspecified target indication would only serve to promote the use of this drug in pediatric patients without any justification."

45. In January 1999, the FDA sent a letter to Janssen regarding Janssen's Risperdal promotional materials and activities that had been reviewed by the Division of Drug Marketing, Advertising and Communications ("DDMAC"). The DDMAC letter concerned Janssen's promotional campaign that marketed Risperdal for use in geriatric patients. The DDMAC concluded that Defendants' marketing materials were false, misleading, lacking in fair balance, and in violation of the Food Drug and Cosmetic Act ("FDCA") and the regulations promulgated thereunder.

46. On March 3, 2000, Janssen met with the FDA to discuss a clinical development plan for an indication for "conduct disorder" in children. Although the FDA recognized that "conduct disorder" is a diagnosis listed in the Diagnostic and Statistical Manual of Mental Disorders, the agency questioned whether it could approve Risperdal for "conduct disorder," explaining that its "main concern is that RISPERDAL or any other product would be used as a chemical straight jacket." In addition, the FDA expressed concern that conduct disorder was "synonymous with aggression" and that Janssen was "trying to get approval of aggression [for children] under the guise of CD [conduct disorder]."

47. In 2001, at the FDA's insistence, the label for Risperdal was modified to include a statement that "The safety and effectiveness in children have not been established." However, Defendants continued to actively and aggressively market and promote Risperdal and Invega for off-label unapproved use in children.

48. In November 2002, the FDA approved a label change providing for the addition of the term "hyperglycemia" to the "ADVERSE REACTIONS: Post-Introduction Reports" section of the Risperdal label. Prior to that there was no mention of hyperglycemia in post-marketing reports in the Risperdal label. The deliberate exclusion of the existence of case reports of hyperglycemia constitutes a failure to adequately warn prescribers and consumers regarding the true risk of diabetes mellitus with Risperdal.

49. Between 1996 and 2006, gynecomastia was characterized by Janssen in its label as a rare event "occurring in fewer than 1/1,000 patients" despite Janssen's knowledge to the contrary obtained through its funded studies.

50. On November 10, 2003, Janssen sent a "Dear Healthcare Provider Letter" ("Provider Letter") to all health care professionals likely to prescribe Risperdal. The Provider Letter deliberately minimized the risks associated with Risperdal and omitted a mandated warning to monitor certain patients on Risperdal.

51. On April 19, 2004, DDMAC issued a warning letter to Defendants concerning the false and misleading Provider Letter and required Defendants to send out a new letter with corrections. According to the FDA, the Provider Letter "misleadingly omits material information about Risperdal, minimizes potentially fatal risks associated with the drug, and claims superior safety to other drugs in its class without adequate substantiation, in violation of Sections 502(a) and 201(n) of the Act (21 U.S.C. §§ 352(a) and 321(n)."

52. Throughout all times herein mentioned, and despite the FDA's warning letters, Defendants continued to systematically conceal, manipulate and misrepresent the risks associated with Risperdal and Invega, including the increased risk of rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), and galactorrhea (lactation).

E. FALSE AND MISLEADING MARKETING AND PROMOTIONS

53. Defendants continually and systematically defrauded health care providers and their patients, including Plaintiff, by promoting Risperdal and Invega for non-approved uses,

failing to account for and report adverse events, and failing to update the drugs' labeling, directions for use, and advertising to account for adverse events.

54. In spite of the specific and limited FDA approval for Risperdal and Invega, Defendants engaged in widespread promotion of Risperdal and Invega for unapproved uses, including use in the child and adolescent market, and concealed, misrepresented and downplayed the risks associated with the use of Risperdal and Invega.

55. As early as 2000, Defendants knew studies they funded concerning the use of Risperdal in children showed heightened risks of rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation) and other adverse conditions yet failed to disclose these heightened risks to the medical community and their patients. Instead, Defendants embarked on an aggressive marketing plan and scheme to create an unapproved adolescent off-label market to increase their market share and profits to the detriment and harm of patients receiving Risperdal and Invega, including Plaintiff.

56. In 2002, despite having no approval from the FDA for Risperdal's use in children, Janssen created a "C&A Educational Initiative" to specifically promote the use of Risperdal in children and adolescents ("C&A"). As part of this Initiative, Janssen developed advisory boards and CME programs and utilized national and regional opinion thought leaders in child psychiatry. For example, in March 2002, Janssen sponsored a meeting attended by 1,000 physicians, which Janssen executives later described as "[a] great way to get the word out to a big part of the child and adolescent prescribing community." Similarly, at an "Advisory Summit" in February 2003, Janssen presented data promoting Risperdal to treat conduct disorders in children with disruptive behavior disorders.

57. When the FDA approved Risperdal M-Tabs for adult use only in April 2003, Janssen district managers encouraged contests and other incentives to promote this quick-dissolving Risperdal formulation in children. For example, in the San Antonio District, district managers encouraged "Risperdal 'Back to School' Bashing" and proposed ice-cream parties,

snacks and lunches as an effective way to deliver an efficacy message of the fast onset of M-Tabs and use in the unapproved pediatric population. Notes from a District Managers' Conference Call on August 11, 2003 stated "There is a very large market for the M-TABs' for children/adolescents!"

58. In an August 20, 2003 Field Conference Report, a Janssen district manager praised a sales representative, stating "You have a great idea for M-Tab starter kits by including lollipops or small toys to be included in the kit along with a coupon and a 1 box of sample. These will be great to use on any child & adolescent psychiatrists that you have.... Plan to have these made for our next work session."

59. At all relevant times, Defendants continued to defraud health care providers and their patients, including Plaintiff, by omitting information concerning the risks of Risperdal and Invega from Defendants' package insert and other labeling, and by utilizing and distributing promotional materials that were false and misleading in that they minimized, misrepresented, downplayed and/or falsified the risks of serious adverse events, failed to advise physicians to monitor patients for these adverse events, and otherwise falsely claimed that Risperdal and Invega was safer and more efficacious than other antipsychotic medications on the market.

60. Defendants engaged in promotional activities that were not only false and misleading as to the safety and efficacy of Risperdal and Invega, but in many cases were also designed to illegally expand the use of the drugs for off-label unapproved uses, without scientific proof of the products' safety and efficacy in treating such disorders.

61. Defendants also engaged in a plan and scheme to manipulate clinical trial data to produce results favorable to Risperdal and Invega and to downplay, misrepresent and hide the adverse risks of Risperdal and Invega.

62. Defendants failed to report negative studies concerning Risperdal and Invega to the FDA, the medical community, and public.

63. Defendants engaged in false and misleading marketing and promotion to conceal, misrepresent and hide the risks associated with Risperdal and Invega from the medical

community, prescribing physicians, and the public by means of the following, among other methods:

a. Hiring medical writers who were not researchers or scientists to write articles and then submitting the articles to selected opinion leaders to attach their names as authors without any meaningful contribution, to lend false credence to these articles in a practice known as ghostwriting;

b. Engaging and paying opinion leaders to bolster the false and misleading practices. Opinion leaders are physicians whose opinions on medical procedures and treatments are held in high regard by other physicians. If these influential physicians are willing to promote the use of a certain drug, then other physicians are likely to follow suit and use that drug, including for off-label unapproved uses which are illegal for the company itself to promote;

c. Presenting false and misleading studies and reports concerning Risperdal and Invega at professional meetings by means of posters and abstracts;

d. Publishing the same studies or selected portions of the same studies in multiple journals to create a false impression of scientific acceptability of Risperdal and Invega for a variety of uses.

e. Conducting marketing and promotion of Risperdal and Invega for off-label use under the guise of continuing medical education;

f. Giving lucrative contracts for “clinical research” as a reward to high prescribers of Risperdal and Invega.

g. Coordinating with consultants, marketing executives, medical staff, healthcare professionals and scientists, to market and promote the off-label use of Risperdal and Invega for the treatment of off-label uses in children including: Attention-Deficit/Hyperactivity Disorder (ADHD), Obsessive-Compulsive Disorder (OCD), Oppositional-Defiant Disorder (ODD), Conduct Disorder (CD), Disruptive Behavior Disorder (DBD), Tourette’s syndrome, pervasive development disorders (PDD), and other conditions.

64. In this way, Defendants consciously and deliberately orchestrated a campaign to profit from Risperdal and Invega beyond the FDA's approved indications for and labeling of the medications.

65. Documents released in connection with settlements, judgments, and plea agreements reached with the U.S. Department of Justice and state attorney generals in their investigation of Defendants marketing of Risperdal and Invega reflect that Defendants concealed side effects of Risperdal and Invega and exaggerated and misrepresented the drugs' effectiveness.

66. Following criminal and civil actions against Defendants, the United States and Defendants entered into a Civil Settlement Agreement which stated in pertinent part:

> "During the period January 1, 1999 through December 31, 2005, Defendants knowingly: (a) promoted the sale and use of Risperdal for conditions and for patients for which it was not approved as safe and effective by the Food and Drug Administration, including the treatment and/or control of: (i) behavioral disturbances in elderly dementia patients, (ii) conduct disorders, attention deficit hyperactivity disorders, and other uses in children and adolescents under the age of 18, (iii) conduct disorders in individuals with mental retardation and developmental disabilities, and (iv) various non-psychotic mental disorders; some of which were not medically accepted indications as defined by 42 U.S.C. section 1396r-8(k)(6)."

67. In 2008, Defendants, through their subsidiary Patriot Pharmaceuticals, began manufacturing, marketing, advertising, selling and distributing risperidone, the generic version of Risperdal, and on information and belief adopted Defendants' practice of off-label promotion of its generic drug.

68. In 2009, Defendant McKesson settled a lawsuit for $350 million that accused McKesson of engaging in a "racketeering enterprise to fraudulently increase the published 'average wholesale price' ('AWP') of over four hundred branded drugs by five percent from late 2001 to 2005." The litigation included McKesson's marketing and distribution of Risperdal.

69. In November 2013, Defendant Johnson & Johnson entered into a $2.2 billion settlement with the U.S. Department of Justice over its false and misleading efforts to market Risperdal and other drugs beyond their federally approved uses.

70. During the investigation and after the settlement, multiple opinion leaders involved in Defendants' marketing of Risperdal rescinded their support and demanded that medical literature written by Defendants bearing the opinion leaders' names be stricken.

PLAINTIFF'S USE OF RISPERDAL AND/OR INVEGA

71. Plaintiff Hofferth was prescribed, ingested and/or injected with Risperdal and/or Invega at various times.

72. While using Risperdal and/or Invega, and as a direct and proximate result thereof, Plaintiff developed serious and/or permanent adverse effects including but not limited to the following: rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), and galactorrhea (lactation).

73. As a result of said injuries, Plaintiff suffered significant bodily and mental injuries; pain and suffering, mental anguish, disfigurement, embarrassment, and inconvenience, and have and will incur past and future medical expenses.

74. Plaintiff used Risperdal and/or Invega manufactured, marketed, sold and/or distributed by Defendants. The Risperdal and/or Invega reached Plaintiff without substantial change in the drug's condition.

75. At all relevant times, Defendants had knowledge that there was a significant increased risk of adverse events associated with Risperdal and Invega and despite this knowledge Defendants continued to manufacture, market, distribute, sell and profit from sales of Risperdal and Invega.

76. Despite such knowledge, Defendants knowingly, purposely and deliberately failed to adequately warn Plaintiff, patients, consumers, medical providers and the public of the increased risk of serious injury associated with using Risperdal or Invega including but not limited to the risks of rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), and galactorrhea (lactation).

77. Plaintiff's prescribing physicians may not have prescribed Risperdal or Invega to Plaintiff had Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of Risperdal and Invega.

78. Plaintiff's prescribing physicians may have changed the way in which the physician treated Plaintiff's relevant conditions, warned Plaintiff about the signs and symptoms of serious adverse effects of Risperdal and Invega, and discussed the true risks of weight gain, hyperglycemia, diabetes mellitus, hyperprolactinemia, gynecomastia, tardive dyskinesia and other serious adverse events.

79. As a direct and proximate result of Defendants negligence, omissions, misrepresentations, failure to warn, willful and intentional acts, and other culpable conduct, Plaintiff suffered significant injuries from the use of Risperdal and/or Invega, including severe and permanent bodily injury, pain and suffering, disability, mental anguish and loss of capacity for the enjoyment of life, and the expense of medical and nursing care.

80. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

DELAYED DISCOVERY

81. Defendants, through their affirmative misrepresentations and omissions, actively concealed from the Plaintiff and Plaintiff's physicians and healthcare providers the true and significant risks associated with Risperdal and Invega.

82. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians and healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

83. No limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between the use of Risperdal and Invega and the harm suffered as a result. As such, Plaintiff hereby invokes the discovery rule based on the fact that this Complaint is filed well within the statutory period after Plaintiff knew or should have known the facts alleged herein.

84. Additionally, the accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

85. Additionally, each Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described in this Complaint.

CAUSES OF ACTION

COUNT I
STRICTS PRODUCTS LIABILITY

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

86. At all relevant and material times, the Defendants designed, manufactured, packaged, marketed, advertised, distributed, and sold Risperdal and Invega, placing the products into the stream of commerce.

87. At all relevant and material times, Risperdal and Invega were designed, manufactured, packaged, marketed, advertised, distributed, and sold by Defendants in a defective and unreasonably dangerous condition.

88. Risperdal and Invega were expected to reach, and did reach, users and consumers, including Plaintiff, without substantial change in their defective and unreasonably dangerous condition.

89. Risperdal and/or Invega were used by Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

90. Risperdal and Invega were defective and unreasonably dangerous when each product entered the stream of commerce in one or more of the following particulars:

a. Risperdal and Invega contained manufacturing defects in that the each product caused and/or increased the risk of experiencing an adverse event, including but not limited to hyperprolactinemia, gynecomastia, and diabetes mellitus.

b. Risperdal and Invega were not safe because the health risks associated with each product outweighed the benefits.

c. Risperdal and Invega were marketed and promoted for use by children and adolescents, when they carried an unreasonable and unnecessary risk of serious injury.

d. Risperdal and Invega were insufficiently and/or inadequately tested by Defendants.

e. Risperdal and Invega were not safe due, in part, to inadequate and defective instructions and inadequate and defective warnings provided by Defendants.

f. Risperdal and Invega were unreasonably dangerous in that, as designed, the risks of serious injury posed by using the products exceeded any benefits the products were designed to or might in fact bestow.

g. Risperdal and Invega were defective in design in that the products neither bore, nor were packaged with, nor were accompanied by, warnings adequate to alert users, including Plaintiff, of the increased risks associated with using the products, including, but not limited to, the risk of serious injury.

h. Risperdal and Invega were not accompanied by adequate warnings and instructions for use that included adequate information to fully apprise users, consumers, and the medical, pharmaceutical and scientific communities of the potential risks and serious side effects associated with using the products.

i. Risperdal and Invega were unsafe for normal or reasonably anticipated use. Said products were defective and unreasonably dangerous in design, construction and/or composition.

j. Risperdal and Invega were defective and unreasonably dangerous because the products did not conform to an express warranty of the manufacturer about the product.

k. Risperdal and Invega were defective and unreasonably dangerous due to inadequate warnings, inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

91. Risperdal and Invega as manufactured and supplied by the Defendants were defective due to inadequate warnings and instructions because, after Defendants knew or should have known of the risk of injuries from use, Defendants failed to provide adequate warnings to the medical community and the consumers to whom the drugs were directly marketed and advertised; and, further, Defendants continued to affirmatively promote Risperdal and Invega as safe and effective.

92. A reasonable person who had actual knowledge of the increased risks associated with using Risperdal and Invega would have concluded that Risperdal and Invega should not have been marketed to or used by children and adolescents.

93. Despite the fact that Defendants knew or should have known of the defective nature of Risperdal and Invega, Defendants continued to design, manufacture and sell Risperdal and Invega so as to maximize sales and profits at the expense of the public health and safety. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by Risperdal and Invega.

94. Plaintiff and the non-defendant health care providers involved could not, through the exercise of reasonable care, have discovered the risk of serious injury associated with and/or caused by Risperdal and Invega.

95. Plaintiff was not aware of the aforementioned defects at any time prior to the injuries caused by Risperdal and Invega.

96. Had adequate information regarding the safety of the products been provided to Plaintiff, Plaintiff would not have used Risperdal and Invega.

97. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

98. As a direct and proximate consequence of Defendants negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands individual judgments against Defendants and seeks compensatory, exemplary and punitive damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT II
NEGLIGENCE

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

99. Defendants negligently manufactured, designed, labeled, packaged, distributed, marketed, advertised, and sold Risperdal and Invega.

100. At all relevant and material times, Defendants had a duty to Plaintiff to exercise reasonable care in the design, manufacture, advertising, marketing, labeling, packaging, distribution, post-market safety monitoring, reporting of adverse events, and sale of Risperdal and Invega, including a duty to insure that the products did not cause users such as Plaintiff to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

101. Defendants breached their duty of care to Plaintiff and were negligent in their actions, misrepresentations, and omissions in numerous ways including the following:

a. Failing to perform adequate testing concerning the safety of Risperdal and Invega which would have shown Risperdal and Invega posed a serious risk of rapid weight gain, hyperprolactinemia, gynecomastia, tardive dyskinesia, and other adverse effects which would have permitted adequate and appropriate warnings to have been by given by Defendants to prescribing physicians and the consuming public, including Plaintiff;

b. Failing to design Risperdal and Invega so as to properly minimize effects on receptors that were known to be associated with certain serious adverse effects;

c. Failing to develop Risperdal and Invega properly so as to minimize the proliferation of new uses for which there was little or no scientific evidence of safety and efficacy;

d. Failing to conduct adequate pre-clinical and clinical testing to determine the safety of Risperdal and Invega, including failing to adequately train clinical investigators as to the risks and benefits of Risperdal and Invega and as to proper methods of monitoring patients;

e. Failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Risperdal and Invega which indicated risks associated with using the products;

f. Failing to conduct adequate post-market monitoring and surveillance of Risperdal and Invega and analysis of adverse event reports;

g. Designing, manufacturing, marketing, advertising, distributing, and selling Risperdal and Invega to consumers, including Plaintiff, without an adequate warning of risks associated with using the products and without proper and adequate instructions to avoid the harm which could foreseeably occur as a result of using the products;

h. Failing to exercise due care when advertising, promoting, and selling Risperdal and Invega;

i. Failing to use due care in the preparation, design and development of Risperdal and Invega to prevent, avoid, or minimize the risk of injury to individuals when the products were used;

j. Failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;

k. Failing to accompany Risperdal and Invega with proper warnings regarding all possible risks associated with using the products;

l. Failing to use due care in the manufacture, inspection, and labeling of Risperdal and Invega to prevent risk of injuries to individuals who used the products;

m. Failing to provide adequate and accurate training and information to the sales representatives who sold the products;

n. Failing to conduct sales of Risperdal and Invega properly in that Defendants' sales representatives made false and misleading statements to prescribers concerning approved and unapproved uses, risks and benefits of Risperdal and Invega;

o. Failing to educate healthcare providers and the public about the safest use of the products;

p. Failing to give healthcare providers adequate information to weigh the risks of serious injury associated with the products;

q. Failing to test and inspect Risperdal and Invega in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, and sold;

r. Failing to warn Plaintiff of the danger of adverse medical conditions from the use of Risperdal and Invega;

s. Failing to label Risperdal and Invega to adequately warn Plaintiff of the serious adverse side effects with the use of Risperdal and Invega; and

t. Failing to refrain from illegal off-label marketing of Risperdal and Invega.

102. Defendants advertised, marketed, sold and distributed Risperdal and Invega despite the fact that Defendants knew or should have known of the increased risks associated with using the products, including but not limited to rapid weight gain, hyperprolactinemia, galactorrhea, gynecomastia, tardive dyskinesia, and other adverse effects of which Plaintiff and his healthcare providers would not have been aware.

103. Defendants, individually and collectively, had a duty to warn the FDA, their customers, the medical community and public about the increased risks of injury but failed to do so.

104. Defendants are guilty of negligence *per se* in that the Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*, and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations.

a. The Defendants' acts and omissions, including but not limited to Defendants' off-label marketing, constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* Persons such as Plaintiff were the parties intended to be protected by such legislation and whose injuries said regulations were designed to prevent. Defendants' conduct was a proximate cause of Plaintiff's injuries.

b. The Defendants' also failed to report adverse events as required by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* Persons such as Plaintiff were the parties intended to be protected by such legislation and whose injuries said regulations were designed to prevent. Defendants' conduct was a proximate cause of Plaintiff's injuries.

105. Despite the fact that Defendant knew or should have known that Risperdal and Invega increased the risk of serious injury including but not limited to rapid weight gain, hyperprolactinemia, gynecomastia, galactorrhea, tardive dyskinesia, and other adverse effects, Defendant continued to manufacture, market, advertise, sell and distribute Risperdal and Invega to consumers, including Plaintiff.

106. Defendants negligently and recklessly represented to Plaintiff, physicians, and other persons and professionals Defendants knew would justifiably rely on the representations, that Risperdal and Invega were safe to use and that the utility of the products outweighed any risk in use for their intended purposes.

107. Defendants negligently and recklessly failed to disclose to Plaintiff and others important safety and efficacy information about Risperdal and Invega, thereby suppressing material facts while under a duty to disclose such information.

108. Defendants' representations about the safety and adverse side effects of Risperdal and Invega were negligently and recklessly made in that Risperdal and Invega in fact caused injury, were unsafe, and the benefits of their use were far outweighed by the risk associated with use thereof.

109. Defendants knew or should have known that their representations and omissions were false. Defendants made such false, negligent and reckless representations and omissions with the intent or purpose that Plaintiff and any non-defendant physicians would rely upon such representations, leading to the use of Risperdal and Invega as described.

110. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Risperdal and Invega, including serious injury. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Risperdal and Invega.

111. At the time Defendants made these misrepresentations and/or omissions, they knew or should have known that Risperdal and Invega were unreasonably dangerous and not what Defendants had represented to Plaintiff, as well as the medical community, the FDA and the consuming public.

112. Defendants' misrepresentations and/or omissions were undertaken with an intent that doctors and patients, including Plaintiff, rely upon them.

113. Plaintiff and his healthcare providers did not know that these representations were false and justifiably relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of Risperdal and Invega to employ these products.

114. As a direct and proximate consequence of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff sustained injuries and damages.

115. Had Plaintiff been aware of the increased risk of side effects associated with Risperdal and Invega and the relative efficacy of Risperdal and Invega compared with other readily available products, Plaintiff would not have used these products.

WHEREFORE, Plaintiff demands individual judgments against Defendants and seek compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III
FAILURE TO WARN

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action, and further alleges:

116. Risperdal and Invega are unreasonably dangerous, even when used in a foreseeable manner as designed and intended by Defendants.

117. Defendants failed to warn and/or adequately warn Plaintiff, consumers, physicians, and healthcare professionals of the increased health risks associated with using Risperdal and Invega.

118. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to them.

119. Defendants had a continuing duty to warn consumers and healthcare professionals of increased health risks associated with its products, and negligently and/or wantonly breached its duty as follows:

a. Failed to include warnings and/or adequate warnings of the increased risks of serious injury associated with using Risperdal and Invega, including but not limited to rapid weight gain, hyperprolactinemia, gynecomastia, galactorrhea, tardive dyskinesia, and other adverse effects;

b. Failed to provide adequate and proper instructions regarding the proper use of Risperdal and Invega to prevent rapid weight gain, hyperprolactinemia, gynecomastia, galactorrhea, tardive dyskinesia, and other adverse effects;

c. Failed to provide adequate and/or proper instructions regarding the need for diagnostic tests to be performed on the patient prior to and during use of Risperdal and Invega to discover and ensure against serious and potentially fatal side effects including but not limited to rapid weight gain, hyperprolactinemia, gynecomastia, galactorrhea, tardive dyskinesia, and other adverse effects;

d. Failed to inform Plaintiff that Risperdal and Invega had not been adequately tested to determine the safety and risks associated with using the products;

e. Failed to warn that the risks associated with the use of Risperdal and Invega exceeded the risks of other available forms of treatment for Plaintiff's conditions, including the risks of rapid weight gain, hyperprolactinemia, gynecomastia, galactorrhea, tardive dyskinesia, and other adverse effects.

f. Failed to report adverse events to the FDA associated with the ingestion and/or injection of Risperdal and Invega;

120. Defendants and each of them had a duty to warn the FDA, the medical community, Plaintiff, and Plaintiff's physicians about the increased risks of injury but failed to do so.

121. Defendants, individually and collectively, had a duty not to engage in illegal off-label promotion of Risperdal and Invega but failed to do so.

122. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiff sustained injuries and damages.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IV
BREACH OF WARRANTY OF MERCHANTABILITY

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

123. Defendants knew and intended that Risperdal and Invega be used by children and adolescents when the products were placed into the stream of commerce.

124. Defendants knew of the use for which Risperdal and Invega were intended and impliedly warranted Risperdal and Invega to be of merchantable quality and safe and fit for their intended use.

125. Plaintiff and his healthcare providers reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and upon the express and/or implied warranty that Risperdal and Invega were safe, of merchantable quality, and fit for use by children and adolescents.

126. The Risperdal and/or Invega used by Plaintiff were not safe, of merchantable quality, or fit for their intended use.

127. The Risperdal and/or Invega used by Plaintiff were neither safe nor fit for use because Risperdal and Invega were and are unreasonably dangerous and unfit for the ordinary purposes for which they are used.

128. As a direct and proximate result of the breach of warranty of merchantability by Defendants, Plaintiff sustained injuries and damages.

WHEREFORE, Plaintiff demands individual judgments against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT V
BREACH OF EXPRESS WARRANTY

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

129. Defendants expressly represented to Plaintiff, consumers and the medical community that Risperdal and Invega were:

a. safe;

b. efficacious;

c. fit for use in children and adolescents;

d. of merchantable quality;

e. adequately tested;

f. well tolerated in adequate and well-controlled clinical studies; and

g. did not increase the risk of experiencing serious, life threatening side effects.

130. Defendants breached the express warranties as follows:

a. Defendants misrepresented the safety of Risperdal and Invega in the products' labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions;

b. Defendants misrepresented the risks associated with using Risperdal and Invega;

c. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury;

d. Defendants misrepresented that Risperdal and Invega were as safe or safer than other available forms of treatment for Plaintiff's conditions; and

e. Defendants fraudulently concealed information about the safety of Risperdal and Invega, including information that the products were not safer than other available forms of treatment for Plaintiff's conditions.

131. Risperdal and Invega did not conform to Defendants' express representations and warranties.

132. At all relevant times, Risperdal and Invega did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

133. At all relevant times, Risperdal and Invega did not perform in accordance with the Defendants' representations because Risperdal and Invega are not safe and cause high levels of serious side effects.

134. In deciding to purchase and use Risperdal and Invega, Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

135. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff sustained injuries and damages.

WHEREFORE, Plaintiff demands individual judgments against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VI
BREACH OF IMPLIED WARRANTY

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

136. At all relevant and material times, Defendants manufactured, distributed, advertised, and sold Risperdal and Invega.

137. Defendants impliedly warranted to Plaintiff that Risperdal and/or Invega were safe for use by Plaintiff and the consuming population.

138. Defendants knew and intended that Risperdal and Invega be used in treatment for children and adolescents when the products were placed into the stream of commerce.

139. Plaintiff and their healthcare providers used Risperdal and Invega as intended and directed by the Defendants and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

140. Plaintiff was a foreseeable user of Defendants' products, Risperdal and Invega. Risperdal and Invega were expected to reach and did in fact reach Plaintiff, without substantial change in the condition in which the products were manufactured and sold by Defendants

141. Plaintiff and his healthcare providers reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and upon the Defendants' implied warranty that Risperdal and Invega were safe, of merchantable quality, and fit for use.

142. The Risperdal and Invega used by Plaintiff were not safe, of merchantable quality, nor fit for use.

143. The Risperdal and Invega used by Plaintiff did not perform in accordance with Defendants' representations because Risperdal and Invega are not safe and both cause high levels of serious, life-threatening side effects.

144. Defendants breached the implied warranty in that Risperdal and Invega did not conform to Defendants' representations.

145. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts described herein, Plaintiff sustained injuries and damages.

WHEREFORE, Plaintiff demands individual judgments against Defendants and seek compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper

COUNT VII
FRAUD

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

146. At all relevant and material times, Defendants expressly and/or impliedly warranted that Risperdal and Invega products were safe, of merchantable quality and fit for use.

147. Defendants' superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of Risperdal and Invega, and its intentional dissemination of promotional and marketing information about Risperdal and Invega for the purpose of maximizing sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the products.

148. At all times herein mentioned, Defendants fraudulently represented to Plaintiff's, physicians, and other persons and professionals whom Defendants knew would justifiably rely on Defendants' representations, as well as the public at large, that Risperdal and Invega were safe and effective for use in treating Plaintiff's conditions.

149. Defendants intentionally failed to disclose to Plaintiff and others important safety, risk, adverse event and injury information, including but not limited to the increased risk of rapid weight gain, hyperprolactinemia, gynecomastia, galactorrhea, tardive dyskinesia, and other adverse effects. Defendants suppressed material facts about the products while having a duty to disclose such information, which duty arose, in part, from the Defendants designing, manufacturing, marketing, advertising, distributing and selling such products.

150. Defendants' false representations were fraudulently made, with the intent or purpose that Plaintiff and healthcare providers involved in providing treatment to Plaintiff would justifiably rely upon them, leading to the use of Risperdal and Invega.

151. Defendants' deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein, include, but are not limited to:

a. Making false and misleading claims regarding the known risks of Risperdal and Invega and suppressing, failing to disclose and mischaracterizing the known risks of Risperdal and Invega, including, but not limited to, rapid weight gain, hyperprolactinemia, gynecomastia, diabetes mellitus, diabetic ketoacidosis, tardive dyskinesia, and death;

b. Making false and misleading written and oral statements that Risperdal and Invega are more effective than other antipsychotic drugs and/or omitting material information showing that Risperdal and Invega are no more effective than other available antipsychotic drugs;

c. Misrepresenting or failing to timely and fully disclose the true results of clinical tests and studies related to Risperdal and Invega;

d. Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of using Risperdal and Invega

which would disclose the nature and extent of the harmful side effects of Risperdal and Invega;

e. Making false and misleading claims that adequate clinical testing had been done and/or failing to disclose that adequate and/or generally accepted standards for pre-clinical and clinical testing had not been followed; and

f. Making false and misleading misrepresentations concerning the safety, efficacy and benefits of Risperdal and Invega without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.

152. Defendants willfully, wantonly, and recklessly disregarded their duty to provide truthful representations regarding the safety and risk of Risperdal and Invega.

153. Defendants made these misrepresentations with the intent that doctors and patients, including Plaintiff, rely upon them.

154. Defendants' misrepresentations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Risperdal and Invega.

155. Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

156. Defendants omitted, misrepresented, suppressed and concealed material facts concerning the dangers and risk of injuries associated with the use of Risperdal and Invega including the increased risk of serious injury as well as the fact that the product was unreasonably dangerous.

157. Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Risperdal and Invega in order to increase sales.

158. Plaintiff and the treating medical community did not know that Defendants' representations were false and/or misleading and justifiably relied on them.

159. Defendants had sole access to material facts concerning the dangers and unreasonable risks of Risperdal and Invega.

160. The intentional concealment of information by Defendants about the substantial risks of serious injury associated with Risperdal and Invega was known by Defendants to be wrongful.

161. Had Defendants not fraudulently concealed such information, Plaintiff would not have used Risperdal and/or Invega.

162. Had Plaintiff been aware of the increased risks of serious injury associated with Risperdal and Invega, Plaintiff would not have used Risperdal or Invega.

163. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which Plaintiff reasonably relied, Plaintiff suffered injuries and damages.

164. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts described herein, Plaintiff sustained the injuries and damages.

WHEREFORE, Plaintiff demands individual judgments against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees and such other, and further relief as this Court deems just and proper.

COUNT VIII
NEGLIGENT MISREPRESENTATION

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

165. Prior to Plaintiff's first doses of Risperdal and/or Invega, and during the period in which Plaintiff used Risperdal and/or Invega, Defendants misrepresented the degree to which Risperdal and Invega provided a safe and effective treatment.

166. Defendants failed to disclose material facts regarding the safety and efficacy of Risperdal and Invega, including information regarding increased adverse events and harmful side effects.

167. Defendants had a duty to provide Plaintiff, physicians, and other patients with true and accurate information and warnings of any known risks and side-effects associated with the Risperdal and Invega products they marketed, distributed, and sold.

168. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failure associated with Risperdal and Invega that their representations regarding these drugs were false, and that they had a duty to disclose the dangers of Risperdal and Invega.

169. Defendants made the representations and otherwise failed to disclose material facts concerning Risperdal and Invega with the intent to induce patients, including Plaintiff, to act in reliance thereon in using Risperdal and/or Invega during the course of their treatment.

170. Plaintiff justifiably relied on Defendants' representations and non-disclosures in choosing to use Risperdal and/or Invega.

171. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff sustained the injuries and damages.

WHEREFORE, Plaintiff demands individual judgments against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth here in full and further prays:

172. So far as the law and this Court allows, Plaintiff demands judgment against each Defendant on each count as follows:

a. Compensatory damages for the described losses with respect to each cause of action;

b. Past medical expenses;

c. Past and future lost wages and loss of earning capacity;

d. Past and future emotional distress;

e. Consequential damages;

f. Disgorgement of profits obtained through unjust enrichment;

g. Restitution;

h. Punitive damages with respect to each cause of action;

i. Reasonable attorneys' fees where recoverable;

j. Costs of this action;

k. Pre-judgment and all other interest recoverable; and

l. Such other additional and further relief as Plaintiff may be entitled to in law or in equity.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated: June 14, 2017

By: s/ E. Hood Temple

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